

Amendment # 5
to RFP-NIH-NIAID-DAIT-02-16
"Bioinformatics Integration Support Contract (BISC)"

Amendment to Solicitation No.:	NIH-NIAID-DAIT-02-16 – Phase II Only
Amendment No.:	Five (5)
Amendment Issue Date:	December 8, 2003
Original RFP Issue Date:	November 20, 2001
Proposal Due Date for PHASE II	February 17, 2004, 3:00 P.M. EST
Issued By:	Barbara A. Shadrick Senior Contracting Officer NIH/NIAID Research Resources Contracts Branch Contract Management Program 6700-B Rockledge Drive MSC 7612, Room 2230 Bethesda, Maryland 20892-7612
Point(s) of Contact:	Lois Eaton, Contract Specialist leaton@niaid.nih.gov David Lisle, Contract Specialist dlisle@niaid.nih.gov
Name and Address of Offeror:	Amendment submitted to: Northrop Grumman (Contract N01-AI-25487) Research Triangle Institute (Contract N01-AI-25486)

The above numbered solicitation is amended to revise the date for receipt of offers; incorporate changes to the guidelines for the submission of the Phase II proposal and provide information regarding the process for review of the prototype. The revised due date is **February 17, 2004**. The time that offers are due remains 3:00 PM EST.

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DAIT-02-16, as heretofore changed, remain unchanged and in full force and effect.

Offerors must acknowledge receipt of this Amendment No. 5, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

PHASE II – Implementation and Operation Statement of Work

The purpose of Phase II is to build and operate the approved version of what was conceived and evaluated in Phase I of this project. In this Phase, the Contractor shall implement and maintain a data repository of genomic, proteomic, and related data from diverse sources. This system shall be comprised of the full array of hardware and software elements determined to be required by participating centers, including but not limited to: (i) databases for data archiving, (ii) servers dedicated to specific tasks, such as web-based communications or on-line data submission, (iii) special stored records, such as personal identifiers, structured vocabularies, or ontologies, (iv) interfaces for machine-machine or human-machine data interchange, and (v) operating systems, middleware, algorithms, and programming languages to be used. In addition, the contractor shall provide bioinformatics technical support and training to assist participating centers with data collection, storage and analysis.

In all material respects this system shall (a) satisfy the scientific data handling needs of basic and clinical immunologists, (b) provide adequate processing and storage capacity for all relevant data sets, (c) furnish data support that accommodates the latest in biomedical research instruments, while permitting the use of advanced methods; and (d) anticipates the complexities of representing biological information. This Phase of the project cannot be conducted without extensive experience and contemporary understanding of basic and clinical life sciences (especially immunology), as well as computer science, systems integration and engineering. This system shall be implemented and maintained by personnel at all levels who are sufficiently experienced in the conduct of biomedical research to conceive and implement solutions in a manner that is understood by and agreeable to biological scientists and clinicians, the end-users of this system.

PHASE II: STATEMENT OF WORK -- (BASE PERIOD OF TWO YEARS)

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the Tasks set forth below.

Specifically, the Contractor shall:

TASK 1. Establish a system for the collection, storage, archive and exchange of clinical and laboratory data from multiple sources and make this accessible to participating end users.

This system will support the analytical requirements of as many as 150 scientists in approximately 115 labs all of whom are using various types of scientific data from disparate sources to understand such matters as: (a) human leukocyte gene (HLA) complex, especially as related to matching transplant donors with recipients, (b) immune tolerance as related to the evaluation of new therapies in kidney transplantation, type I diabetes islet transplantation, autoimmune disease, asthma and allergy, (c) hematopoietic stem cell transplantation, and (d) studies of a variety of promising allergen-specific and non-specific immune-based therapies. The system will serve a distributed, multidisciplinary community of basic and clinical researchers. Please note that this system will not replace the activities and functions of established DAIT clinical trials coordinating centers. The system will store clinical trials data after the completion and primary publication of the trials.

This shall include, but not be limited to:

- (a) Designing and implementing the architecture for a widely distributed networked system for biomedical scientific data collection, storage and exchange;
- (b) Creating an electronic data repository containing all available scientific data for each research subject, including but not limited to, clinical and diagnostic information in those areas specified by end users. Genomic data to be archived or accessed by the system shall include: sequence data, expression data, single nucleotide polymorphism data, protein structure, and pathway data. Proteomic data will include molecular-level records on all biologically active substances – amino acid, peptide, and protein structure -- as generated by numerous experimental methods. All such data shall be maintained in electronic databases in a format that permits rapid and efficient production of files for distribution in formats specified by the requestor. The Contractor shall carefully verify all data in collaboration with the participating laboratories on the grants or contracts under which the data were collected.

- (c) Developing, implementing, and/or disseminating software applications to make these data accessible to end users according to their needs and constraints and in accordance with the timelines detailed in the NIH Data Sharing Policy (http://grants2.nih.gov/grants/policy/data_sharing/index.htm);
- (d) Allowing for the integration of legacy data from relevant sources (both public and private), the future acquisition of high-quality data, and the computer-based analysis of those data;
- (e) Developing and disseminating protocols and standards for the collection, archiving, and exchange of these biomedical data;
- (f) Developing applications for the collection, submission archiving, analysis and exchange of these biomedical data;
- (g) Providing technical assistance in the collection, submission, exchange and analysis of data;
- (h) Designing and implementing a reliable system of quality control applied to all data and media;
- (i) Developing uniform, intelligent web-based interfaces for remote data entry by human users;
- (j) Assisting participating labs with submission of normalized, high quality data;
- (k) Developing and implementing a long range plan for the long term maintenance and survival of the data; and,
- (l) Integrating system updates according to changing technological advances and user needs.

Successful completion of the above shall require the Contractor to: (i) design, implement and maintain a scaleable architecture for representing, acquiring, and storing data of many types, including but not limited to, genetic, cellular, molecular, and clinical; (ii) rapidly disseminate software for the capture, analysis, query, and storage of genomic and related data; (iii) link to other relevant existing data sources and support the integration and analysis of those data sets; (iv) enable researchers to share data and analytical tools more readily through a variety of methods such as the dissemination of software standards; and (v) creatively use client-server, peer-to-peer, and/or computer-mediated architectures to adjust the system to end-user needs and constraints.

The Contractor shall develop and disseminate applications that enable scientists working independently in participating programs to generate, normalize, archive, and exchange data of all types easily and without risk of data corruption. The Contractor shall draw on the latest advances in software engineering and computer sciences and translate those advances into practical tools that are easily used by the target users in this project. The software development to be conducted under this task shall integrate rather than displace existing applications. The Contractor shall develop, acquire, and disseminate applications as appropriate that address what NIAID has determined to be the most pressing needs of participating centers, which include but are not limited to: (i) improved processes and interfaces (human-machine and machine-machine) for data submission and exchange, (ii) common standards of knowledge representation to enable cross-platform portability of research data, (iii) translation middleware to extend the usability of large legacy data sets, and (iv) controlled access and data sharing protocols to protect records under complex human subjects or intellectual property constraints.

The Contractor shall distribute electronic files of clinical, diagnostic and laboratory data only with the prior written approval of the NIAID Project Officer, and in accordance with current Federal and State regulations.

The Contractor shall ensure that software applications and standards facilitate the interoperability of the data systems and/or the portability of data. All novel software developed under this contract shall be licensed without cost to the Federal Government. The Government may disseminate that software as it chooses.

The Contractor agrees that work on this project will not be delayed at any point due to disagreements regarding Intellectual Property either between the Government and the Contractor or between the Contractor and its subcontractor(s).

The Contractor and its subcontractor(s) shall not use any data that are archived, curated, or otherwise obtained under this contract for their own purposes without the express written permission of the NIAID Project Officer.

TASK 2. Lead system and data integration for diverse sets of genomic, proteomic, clinical, and other data that shall include but not be limited to the following:

- (a) Designing and implementing a widely distributed on-line scientific data query system (specifically allowing query of legacy, genomic, and proteomic data in accordance with end-user needs);
- (b) Developing and implementing a plan to ensure the usability, interoperability, survivability, and portability of all data sets (including but not limited to elispot, tetramer, microarray, flow cytometry, and mass spectroscopy data from various sources);
- (c) Developing a data base translation system and tools to integrate and query across several archives;
- (d) Disseminating information on the system capabilities and training participating labs on the system and its use procedures.

In conducting this work, the contractor shall:

- (a) Employ the latest technologies and methods. The contractor shall draw upon current information technology developments in the clinical informatics and computational biology communities, where new interfaces, curation tools, and middleware are being developed to serve the special needs of life scientists for advanced data representation and computational analysis of genomic, proteomic and related data. The contractor shall select and extend the best and most appropriate solutions from these domains to better serve the immunology community.

The Contractor shall also make extensive use of the latest technologies for representing, archiving, and analyzing biological and chemical data in order to define, implement, and maintain a database that models essential aspects of the immune phenomena of interest to participating researchers. In particular, the Contractor shall apply extensive biological knowledge to integrate elispot, tetramer, microarray, flow cytometry, and mass spectroscopy data because each of these instruments plays a critical role in genome- and proteome-based discovery.

- (b) Remain aware of the special needs of scientists in this domain and update the system accordingly. The Contractor shall develop the system in keeping with the special challenges arising with the integration of clinical, genomic and proteomic data.

TASK 3. Provide ongoing technical assistance to each of the participating labs with the local analysis of their data. This shall involve the following:

- (a) Providing ongoing technical assistance in the collection, submission, and accessing of data relevant to the common research interests of participating labs. This technical assistance shall extend to methodological assistance in biostatistics and research design only where it is critical to the quality and utility of data used in this network;
- (b) Advising on the selection and use of software and hardware for data collection and analysis;
- (c) Providing information and software to assist laboratories in the collection and normalization of data;
- (d) Providing assistance in technology selection to see that tools adopted locally for data capture and analysis are of the best quality;
- (e) Providing assistance in setting standards to see that the local nomenclature and data representations are coordinated with those used centrally; and
- (f) Training bioinformatics professionals at participating labs in order to ensure that all applications and services are fully understood and operational at the local labs.

TASK 4. Develop and implement a system for monitoring security and system performance with the aim of maintaining data security and integrity, as well as high levels of service to end users.

- (a) Develop a program and needed applications for monitoring use of the system;
- (b) Develop and implement a plan to protect data derived from human subjects in compliance with, and keeping up with current regulations;
- (c) Test the system according to best and standard practices in computer and engineering services to ensure that it is performing according to service levels agreed to at the time of award;
- (d) Report on and repair any potential problems with the system;
- (e) Inform and train users in the security procedures of the system; and,
- (f) Develop, implement, and maintain security requirements, including:
 - 1) An Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); and, the Continuity of Operations Plan (COOP)(also known as the Contingency Plan);
 - 2) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls; and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting purposes;
 - 3) The preparation and submission, for Project Officer approval, of an RA following the guidance given in DHHS AISSP Handbook (<http://irm.cit.nih.gov/policy/aissp.html>). The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements;
 - 4) The preparation and submission of an annual SSP, following the instruction in OMB Bulletin 90-08, for review and approval by the Project Officer and the NIH SSO (<http://irm.cit.nih.gov/itmra/omb90-08.html>);
 - 5) The development and maintenance of an up-to-date COOP following the guidance in DHHS AISSP Handbook (<http://irm.cit.nih.gov/policy/aissp.html>). At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months;
 - 6) Plans, procedures, and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from clinical and basic research study sites. This includes data integrity and security during electronic transmission, or during transit from the sites to the BISC if non-electronic data transmission is used. All patient identifiable data is subject to the Privacy Act and HIPPA regulations; and
 - 7) Provision for the appropriate labeling, storage, handling, and disposal of sensitive or controlled data, media, and output.

TASK 5. Communicate regularly with the NIAID Project Officer and the leadership of participating centers throughout the contract period of performance.

- (a) Develop a plan for obtaining regular end user feedback and promoting the BISC system within the biomedical research community and with NIAID program staff. The plan shall include;
 - 1) mechanisms for ongoing input into subsequent versions of the system from participating users for continuous improvement to the system;

- 2) rapid dissemination of new methods and tools developed under this contract (including training) to the user community; and,
 - 3) coaching, guidance, and instruction in the BISC system and upon request, bioinformatics in general.
- (b) Collaborate with the NIAID Project Officer and the leadership of participating labs to address key information policy issues relevant to the performance of this contract including, but not limited to, (1) data access and release; (2) standard nomenclature; (3) data submission and dissemination formats; (4) data security policy; and, (5) intellectual property.
- (c) At the request of the NIAID Project Officer, conduct individual and group working meetings with the leadership of participating labs, BISC staff, and NIAID program staff. Group meetings shall occur no less frequently than one meeting per year.

TASK 6. Within sixty days (60) of the end of contract base period, the Government shall notify the contractor of its decision to either exercise the option to continue the contract or close out the project.

The Contractor shall make available to a successor contractor or to the Government, all programs, documents, other contract-related materials, as well as any Government Furnished Equipment and Software. These materials shall be organized and catalogued in sufficient detail to support an orderly transition to the successor contractor or to the Government. The Contractor shall prepare a transition plan that details access to the BISC system, accumulated data, software tools, and equipment that will be transferred in an orderly manner to the Government or a subsequent contractor upon completion of the contract. The Contractor shall work with the Project Officer and Contracting Officer to refine and complete this plan. The plan shall include, but not be limited to: a comprehensive inventory of all the data, websites, software tools, and technology developed, accumulated, and distributed during the contract's performance as well as a list containing detailed descriptions of any process documentation (e.g., hard copy and electronic versions of all standard operating procedures) developed during the contract's performance. The plan shall also include the recommended steps necessary for a successful transition of hardware and software to a subsequent contractor in order to sustain the activities provided for in the contract. The contractor shall work with the new contractor or the Government to insure an orderly transition and will assure the dedication of appropriate personnel to manage and provide oversight of the transition.

[END OF PHASE II – BASE PERIOD STATEMENT OF WORK]

PHASE II: STATEMENT OF WORK -- (OPTION PERIOD OF FOUR YEARS)

- TASK 1.** Within thirty (30) days after the initiation of the option, provide and submit for approval of the Project Officer a Revised Project Management Plan that defines the critical path for the option's statement of work, including: key objectives; technical approach; proposed time schedule of major activities; decision-making criteria; and specific development tasks. The Plan shall include well-described, quantifiable, feasibility criteria with a discussion of the implications of successful completion of these criteria during performance of the statement of work.
- TASK 2.** Perform TASKS 1. through 6. of the Phase II (Base Period), Statement of Work, above.
- TASK 3.** Ensure an orderly and timely transfer of all data, information, and contract-related materials to a successor contractor or the Government. Six months prior to the contract completion date, a transition plan shall be submitted to the Project Officer for approval.

[END OF PHASE II – OPTION PERIOD STATEMENT OF WORK]

Bioinformatics Integration Support Contract (BISC)
DAIT-02-16

PHASE II - Implementation and Operation
Deliverables, Reporting Requirements and Milestones

For the entire duration of Phase II (regardless of whether the Phase II Option is exercised), the Contractor shall submit an original and three (3) copies of each of the items listed below. The schedule for delivery for these items (approximated here) is subject to change based on agreement by the NIAID Project Officer and the Contractor. The completeness and acceptability of all deliverables will be determined by the NIAID Project Officer at his or her sole discretion and in consultation with representatives of participating NIAID research centers.

- (a) Phase II Project Management Plan: This Plan shall define the milestones for the Phase II Statement of Work, including; key objectives; technical approach; proposed time schedule of major activities; decision-making criteria; and specific project strategy. The Plan shall include well-described, quantifiable and feasible milestones, approximate project start and production dates, identification of dependent applications, level of effort required, special software licenses or hardware expenses and overall cost, and planned and actual budget and timelines for completion of this project, as well as a means of monitoring and reporting performance on all parts of the work statement. The first Plan shall be due thirty (30) days after contract award. Updates will be submitted at quarterly intervals; thereafter, for the duration of the project and shall be due on/before the 10th of the month following each quarter.
- (b) Monthly Progress Report: The contractor shall provide a Monthly Progress Report to the NIAID Project Officer that describes the Contractor's activities for the previous thirty (30) day performance period. The Report shall include an overview of progress toward the goals of this RFP, a summary of activities planned for the next reporting period, significant staffing changes since the last reporting period and problems and/or issues encountered or anticipated in the execution of this RFP. The report shall be due on/before the 5th of the month following each monthly reporting period.
- (c) Annual Site Visit: Every 12 months after contract award, the Contractor shall provide a demonstration of a fully operable system of databases including interfaces for data collection, data models, and ontologies or structured vocabularies, as well as initial documentation for all hardware and software. This site visit will be conducted by the Project Officer to the Contractor's site. The Contractor shall regularly update and refine these deliverables in accordance with end-user requirements. These modifications and appropriate measures of their impact shall be reported at least annually to NIAID Project Officer.
- (d) Annual Progress Report: An annual report and requirements update shall be provided to the NIAID Project Officer on/before the 30th of the month following each anniversary date of the contract. This report shall provide documentation that all feasible aspects of the system implementation plan have been executed or that reasonable alternative approaches to the execution of this plan have been carried out. Requirements updates shall address all issues that may arise due to modified or newly discovered requirements; they shall also address software lifecycle issues. This report shall explain benefits delivered by the system of databases and technical support work, discuss any barriers to implementation and how they have been addressed, discuss the current and needed functions of the platform based on a thorough understanding of end-user requirements, and include the annual Automated Information System Security Report;
- (e) Final Report (Base Period): This Report shall be submitted by the Contractor three months prior to the completion date of the contract's base period. This report is to include a summation of the work performed and results obtained for the entire base period of performance (as identified in the contract). This report shall be in sufficient detail to describe comprehensively the results achieved and plans for continued performance during the Option period and will be used by the Contracting Officer and Project Officer to make the final determination to exercise the next Option under this contract. If the Option is not exercised, this report will serve as the Final Report under this contract. No other deliverables will be required for the period when the Interim Final Report is due.

The Contractor shall submit, with the Interim Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

- (f) Final Report and Summary of Salient Results: This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with ARTICLE F.1 DELIVERIES of this contract. No other deliverables will be required for the period when the Final Report is due. The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This deliverable is due on/before the completion date of the contract.

**Bioinformatics Integration Support Contract (BISC)
DAIT-02-16**

**PHASE II
TECHNICAL EVALUATION FACTORS FOR AWARD**

THIS SECTION PERTAINS TO THE EVALUATION OF THE PHASE II – IMPLEMENTATION AND OPERATION, PORTION OF THIS PROJECT. THE BELOW EVALUATION CRITERIA WILL BE UTILIZED TO EVALUATE THE PHASE I DELIVERABLES, WHICH INCLUDE: THE REQUIREMENTS ASSESSMENT, THE ENVISIONED FUTURE SYSTEM, A DEMONSTRATION OF THE WORKING PROTOTYPE OF THE SYSTEM, AND A PLAN FOR IMPLEMENTING AND MAINTAINING THE SYSTEM (INCLUDING A COMPLETE TECHNICAL AND BUSINESS PLAN FOR PHASE II).

1. GENERAL

Selection of an Offeror for contract award in Phase II will be based on an evaluation of proposals against two factors. The factors in order of importance are: Technical, Cost/Price. Although technical factors are of paramount consideration in the award of the contract, cost/price is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

The following technical evaluation factors pertain to the entire Phase II Statement of Work.

The evaluation will be based on the demonstrated capabilities of the prospective Contractor(s) in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions and periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interest. Evaluation of the options will not obligate the Government to exercise the options.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material and the working prototype system provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

OFFEROR(S) AND REVIEWERS ARE ADVISED TO REFER TO THE PHASE II "ADDITIONAL INFORMATION ON THE SCOPE AND REQUIREMENTS OF THE SOLICITATION" SECTION OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.

The demonstrated evidence of capability should include current and/or past related work experience, activities and deliverables related to these requirements, and the qualifications, availability, and experience of the professional and technical personnel necessary to perform contract requirements. Proposals will be evaluated based on the following factors:

CRITERIA – PHASE II	WEIGHT
A. TECHNICAL APPROACH	35
<p>The offeror will be evaluated based on the technical and /or scientific merit, appropriateness and feasibility of the proposed plans and demonstrated capability to carry out the tasks outlined in the Statement of Work including:</p>	
<ol style="list-style-type: none"> 1. Developing and operating a system to serve the data analysis and management requirements of a large, heterogeneous, and widely distributed research community; 2. Leading implementation of large-scale projects for systems design and data integration in a life sciences research and clinical setting. Includes ability to work in a coordinated and efficient manner with subcontractors and participating centers over the life of the project; 3. Providing ongoing technical assistance to a large, heterogeneous research community, including the local analysis of data; 4. Developing and implementing new software applications and integrate existing ones, especially where the analysis, storage, and exchange of scientific data are concerned; 5. Developing and implementing a plan for monitoring systems security and a plan for monitoring system performance; 6. Developing and implementing a plan to obtain feedback from users and promote BISC activities with the NIAID and the participating centers throughout the contract period of performance. 	
B. UNDERSTANDING THE SCOPE	25
<p>DAIT objectives for this RFP are to enhance scientific discovery through improving the testing of new therapies; ensuring the responsible management of research assets; and adding value to existing DAIT research programs through activities such as providing analysis tools, bioinformatics advice and data integration across studies. The suitability of an offeror to conduct Phase II of this project will be judged within the context of those objectives and by the scientific and technical merit, appropriateness and feasibility of the proposed:</p>	
<ol style="list-style-type: none"> 1. Specification of requirements of the envisioned future system. 2. System design of the envisioned future system. 3. Plan for implementing the envisioned future system. 4. Transition plan. 	
C. WORKING PROTOTYPE	10
<p>The Offerors will be evaluated based on the scientific merit, feasibility and appropriateness of the working prototype to meet the needs of the DAIT research community. The prototype will be evaluated on tools provided for one or more of the scientific areas of focus for the DAIT: asthma, autoimmunity, type I diabetes or immune tolerance. Specifically, the working prototype will be evaluated on the functionality of:</p>	

1. a set of integration tools and data models to build a data repository of information from a variety of DAIT clinical and basic research studies;
2. a representative set of data analysis tools;
3. processes for access control;
4. processes for data quality control;
5. processes for data tracking and data archive; and
6. user documentation.

D. PERSONNEL

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The suitability of proposed staff as demonstrated by their documented relevant qualifications, training, expertise, knowledge, experience, education, competence, and availability to perform the requirements of the work statement, including

1. Basic and Clinical Life Sciences Research:
 - a) the conduct of clinical and basic biomedical research and documented ability to translate that knowledge into information systems which improve life science data acquisition, analysis and dissemination;
 - b) Developing, operating and improving bioinformatics, biostatistics, chem-informatics, and laboratory automation, including knowledge of laboratory information management systems (LIMS) and all other computer-based methods of data collection and management; and,
 - c) the application of policies concerning the protection of human subjects in life science research as they pertain both to biological samples and information.
2. Computer Science, Systems Integration and Engineering
 - a) Designing, developing and familiarity with a wide range of computer-based algorithmic approaches to querying and analyzing data;
 - b) Supporting computer systems required to generate and analyze life science research data; and,
 - c) The application of best practices in the industry for systems integration, software engineering and project management.
3. Leadership ability and level of effort
 - a) The suitability of the Principal Investigator/Project Director and the surrounding leadership of the organization to successfully plan and manage the project.
 - b) The suitability of documented related experience and leadership capability of proposed key personnel in both computer sciences and life sciences relevant to this project and scientific interests of DAIT.
 - c) The suitability of the demonstrated involvement of the proposed Principal Investigator/Project Director and key personnel in the scientific communities that are currently conducting clinical and basic research in allergy, immunology, and transplantation.

E. FACILITIES

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Evaluate the proposed facilities as described with respect to:

1. The availability, accessibility and adequacy of proposed facilities consistent with the requirements described in the statement of work that will enable the Offeror to efficiently serve a scientific community based in the continental United States;

2. The suitability of the documented access to all equipment and resources necessary for performance of the contract including but not limited to special resources essential to the development and testing of software and systems that address project requirements, test beds, selected software development environments, and engineering methods consistent with best practices or emerging standards;
3. The suitability of the documented capacity for material and data distribution, including but not limited to: telecommunications infrastructure and server capacity, established methods for avoiding data loss and corruption, and for tracking errors in the handling of materials, communications planning and capacity, and facilitating scientific communication and collaboration through advanced network-based technology;
4. The suitability of the physical plant(s) where valuable, sensitive, and proprietary data are routinely generated, used, and exchanged. This includes the suitability of documented and tested information policies governing privacy, human subjects protection, and data access, as well as the exchange, disclosure, and ownership of scientific data; and;
5. The suitability of assurances that the information policies of participating individuals, laboratories, and institutions are conducive to the full implementation and operation of the envisioned system.

TOTAL POINTS

100

INSTRUCTIONS TO OFFERORS FOR PHASE II

GUIDELINES FOR PEER REVIEW OF PROTOTYPE

- Prototypes shall be housed on each offeror's own servers.
- Offerors are required to provide anonymized access to the Contracting Officer and the Project Officer to the prototype.
- Offerors shall not track the activity of the reviewers in reviewing the prototype.
- Offerors must agree to "do no harm" to the systems or equipment of the reviewers.
- Offerors are required to provide this access from the date of submission to within at least 1 week prior to the review meeting. *[Date of review will be provided by the Contract Specialist to the offerors after receipt of proposal.]*
- Offerors are required to provide an optimal and minimal configuration for the reviewers to access the systems. (i.e. Windows XP, Pentium III, etc.).
- Offerors are required to freeze the prototype code and data on the date of Phase II submission. Code will be date and time stamped when frozen and delivered to the Government upon request. ***Violation of the freeze without Contracting Officer approval will invalidate the proposal.***
- Changes to the code may only be allowed to fix unanticipated major problems that are blocking the reviewers from reviewing the prototypes. All such fixes are required to be cleared through the Contracting Officer and documented fully including the date of the fix. The documentation shall be turned in to the Contracting Officer within two (2) working days following such fixes.
- Trouble reports are required to be submitted by the Reviewers to the Contracting Officer, the Contract Specialist or the Project Officer. These NIAID representatives will then arrange a conference call between the offeror(s), the reviewer, and the NIAID representative(s).
- Offerors are required to include a user manual to assist the panel in reviewing the prototype.
- Offerors will be given a half hour at the reverse site visit to do a quick demo of the system and another half hour to answer the questions from the reviewers that were previously given to the offeror. Offerors will then leave and the formal review will take place. Demonstrated prototypes must be those frozen at the time of submission other than any changes authorized by the Contracting officer.
- NIH IT staff will be on hand to handle any technical issues associated with NIH equipment or network during the entire period that the proposals are made available to the Reviewers and during the conduct of the Peer Review Meeting.

[END OF AMENDMENT #5]